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The use of Netcell and Rapid-Rhino nasal packing after routine nasal surgery. A randomised controlled trial.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 12/02/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0203157782

Study information

Scientific Title

Study objectives
In patients who have nasal surgery requiring nasal packing, which nose pack is the least uncomfortable to have removed: Netcell or Rapid-Rhino?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Nasal

Interventions
Patients meeting the inclusion criteria will be recruited into a randomised controlled trial, in which one nasal cavity is packed with Netcel, and the other with Rapid-Rhino.

Patients deemed suitable will be approached for their consent to participate in the trial. A record of all such patients will be kept, along with reasons for the decline to take part if this occurs, in line with the CONSORT recommendations. All patient-sensitive data stored will be anonymous.

Randomisation
This will occur at the end of the procedure, when the surgeon decides to definitely pack both sides of the nose. If this is desired, the pack chosen for the left nostril would be selected by telephone randomisation. The pack chosen for the right nostril would be, by default, the other type of pack.

Removal of packs
As per current departmental practice, the packs will be removed by the nursing staff at 7am the following morning. Five minutes prior to removal, and immediately following removal, patients will record their pain scores on a standard 10cm visual analogue scale (an unmarked line), with the 2 ends to signify no pain and the most severe pain imaginable. Patients will mark the same line for both the left and right sides of the nose, and label each mark accordingly. The scales for the pre- and post- removal scores will be on opposite sides of a piece of paper to avoid the scores influencing one another. The left pack will always be removed first. It is possible that the order in which the packs are removed could influence the level of pain felt when the two sides are compared. Always removing the left pack first will ensure that this source of bias is eliminated.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Difference in mean Visual analogue score (VAS) on removal of pack

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/02/2005

Completion date
02/08/2005

Eligibility

Key inclusion criteria
Patients having septal surgery and trimming of inferior turbinates will be identified when they attend for pre-assessment clinic. They will be given the information about the trial at that point and given time to consider if they wish to take part before signing the consent form. Inclusion criteria will include:
1. Patients aged 16-65. Children and older adults excluded as pain responses are known to differ at extremes of age.
2. Patients undergoing septal surgery with bilateral inferior turbinate surgery. All consultants in the department routinely pack following this procedure, whereas preferences differ for other nasal operations.
This limited inclusion criterion also ensures that the same operation is carried out on each side of the nose.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
45

Key exclusion criteria
1. Revision surgery
2. History of a bleeding tendency
3. Patients on anticoagulants or anti-platelet drugs
4. History of sino-nasal trauma
5. Underlying systemic/sino-nasal disease such as Wegner's disease, sarcoidosis, fungal sinusitis

Date of first enrolment
02/02/2005

Date of final enrolment
02/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Royal Devon & Exeter Healthcare NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2009		Yes	No